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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/978,593	10/18/2001	Nana K. Ayisi	S&B-C161	5237

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EXAMINER	
WINKLER, ULRIKE	
ART UNIT	**PAPER NUMBER**
1648	

DATE MAILED: 02/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action Before the Filing of an Appeal Brief	**Application No.** 09/978,593	**Applicant(s)** AYISI, NANA K.	
	Examiner Ulrike Winkler	**Art Unit** 1648	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 09 November 2004 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
   a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
   b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) a set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The reply was filed after the date of filing a Notice of Appeal, but prior to the date of filing an appeal brief. The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appea has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☐ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: _____.
   Claim(s) objected to: _____.
   Claim(s) rejected: _____.
   Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: see attached.
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08 or PTO-1449) Paper No(s). _____
13. ☐ Other: _____.

Applicants' arguments and the Offices response are essentially the same of record. In response to Applicant's arguments, addressing the 35 USC § 112 rejection, that MPEP § 2164.02 does not require a rigorous or invariable exact correlation between the *in vitro* and *in vivo* model [citing Cross v. Iizuka, 224 USPQ 739 (Fed Cir. 1985)]. *In vitro* testing permits an investigator to establish the potency of a compound with respect to the particular pharmacological activity. In this case when treating HIV it is well established in the art that what is observed in the test tube does not necessarily pan out as treatment method in the patient, this was exemplified in the case of Suramin discussed in the Office action of October 21, 2003, page 6. Even when using well-known cell lines, the information obtained from the cell lines does not necessarily provide any information regarding effect of the product *in vivo.* In the HIV art there are numerous examples in which laboratory strains of the virus are used for testing purposes in the lab and the products are effective in the *in vitro* setting. However, the effectiveness of the treatment tested *in vitro* has not panned out in the clinical setting where the virus in a patient is wild type virus and not the laboratory strain. The best example comes form the repeated efforts of trying to develop vaccine for the purpose of antibody production in the patient that would be effective at preventing viral entry in the cells *in vivo*. These antibodies, although effective against the laboratory strains, have not proven effective *in vivo* against wild type virus in the environment. The Office recognizes that FDA approval is not a prerequisite for finding utility (25 U.S.C. § 101) for purposes of patentability as pointed in In re Brana, 34 USPQ 2d 1436 (Fed. Cir. 1995). In this case utility was not questioned, the instant claims are rejected for failure to teach "how to use" the claimed invention in the unpredictable art of viral treatments.

Applicants' arguments and the Offices response are essentially the same of record. In response to Applicant's arguments, addressing the 35 USC § 102 rejection, that a claim is anticipated only if each and every element is expressly or inherently described in the art reference (MPEP 2131) and a reference contains an enabling disclosure if the public was in possession of the claimed invention before the date of the invention (MPEP 2121.01). In this instant the prior art discloses the decoction (boiling leaves in water like tea) of *O. gratissimum* for the treatment of fever and diaphoretic and also as a stomachic laxative. Applicants' arguments are that the reference only discloses the preparation and testing of (a) an aqueous extract of the whole plant (b) the essential oil and (c) an aqueous solution of the essential oil for the ability to inhibit bacterial growth. The reference does not disclose anti-viral testing and/or a method of use *O. gratissimumfor* inhibiting the cytopathic effects of a virus infected cell. In response, where a method of the prior art is performed on either the same population or a subset of the same population as the claimed method using the same material and methodology, the prior art method inherently would achieve whatever desired outcome was discovered and claimed by applicant. In this instance Nigerian people used an infusion of the *O. gratissimum* for the purpose of treating fevers, fevers are a response by the body to combat bacterial or viral infections. Though the Nigerian patient may not have appreciated the nuance that a compound found in the plant actually has a cytophatic effect on a virus in a test tube. The purpose of drinking the infusion of *O. gratissimum* by a patient is to help the patient get well. Applicants are asking that the Office grant them a patent where the Nigerian patient, who happens to be infected with a virus, would be infringing the instant claim by drinking tea made from *O.*

gratissimum. Applicants' arguments have not been found persuasive and the rejection is maintained for reasons of record.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG (November 15, 1989). The Group 1600 Official Fax number is: (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Tech Center representative whose telephone number is (571)-272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ulrike Winkler, Ph.D. whose telephone number is 571-272-0912. The examiner can normally be reached M-F, 8:30 am - 5 pm. The examiner can also be reached via email [ulrike.winkler@uspto.gov].

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached at 571-272-0902.

ULRIKE WINKLER, PH.D.
PRIMARY EXAMINER 2/9/05